

REMARKS

Claims 1 – 8, 10 – 22, 24 – 28 and 30 -32 are pending in this application with claims 1 – 3 and 20 being withdrawn from consideration. Claims 6 – 8, 10, 11, 13 and 21 are amended and claims 4, 22, 24, 25 and 30 – 33 are cancelled by this response.

Claims 5 and 12 have been indicated in the Office Action as being allowed.

Claims 6 – 8, 10 and 11 have been formally amended to be dependent on allowed claim 5. Claim 11 has been further amended to include “a composition having the chemical formula NaHCO3” in the list of “active ingredients” claimed in claim 10. Support for this amendment can be found in the first line on page 13 of the present specification as well as in the originally filed claims. Therefore, Applicant respectfully submits that no new matter is added by this amendment. Thus, it is respectfully submitted that as claims 6 – 8, 10 and 11 are dependent on allowed claim 5, claims 6 – 8, 10 and 11 are in condition for allowance.

Claim 13 has been amended to remove “ethyl alcohol” and “propylene glycol” from the list of carriers in the claimed invention.

Claim 21 has been amended to include similar features as recited in allowed claim 5 and thus is likewise allowable. As claims 26 – 28 are dependent on independent claim 21, it is respectfully submitted that claims 21 and 26 – 28 are in condition for allowance.

Rejection of Claims 4, 6-8, 10 – 11, 13 - 19, 21 – 22, 24 – 28 and 30 - 33 under 35**U.S.C. 112, first paragraph**

Claims 4, 6-8, 10 – 11, 13 - 19, 21 – 22, 24 – 28 and 30 - 33 stand rejected under 35 U.S.C. 112, first paragraph as not meeting the enablement requirement.

Claims 4, 22, 24, 25 and 30 – 33 are cancelled by this response and claims 6 – 8, 10 and 11 have been amended to be dependent on allowed independent claim 5. Additionally, claim 21 has been amended to include the allowable limitation of “an anti-itch enzyme” therein with claims 26 – 28 being amended to be dependent on now allowable independent claim 21. Therefore, in view of the above remarks and amendments to the claims, Applicant respectfully submits that the rejection under 35 USC 112 first paragraph with respect to claims 4, 6 – 8, 10, 11, 21, 22, 24 – 28 and 30 – 33 is now moot and should be withdrawn.

With respect to claims 13 – 19, Applicant respectfully disagrees with the assertion made by the Office Action with respect to enablement of these claims. Specifically, the Office Action states that the specification does not provide enabling disclosure for the use of an abrasive and carrier with any anti-itch enzyme as “a composition for relieving itch, pain and swelling” associated with an insect sting or bite. Applicant respectfully disagrees. The specification clearly enables the present claimed invention to operate without requiring undue experimentation to achieve the claimed results. The present invention provides relief for insect bites and/or stings in the form of a composition including an “effective amount of abrasive ingredient” and “an effective amount of an anti-itch enzyme” which “upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site is able to at said site”. As stated on page 7 of the present specification (and referenced numerous times in prior responses), the claimed composition “is rubbed directly on the skin” and “draw[s] the allergenic or

poisonous substance from the affected area along with any body materials resulting from swelling or infection". Additionally, “[n]ot only is the itch relieved by way of the enzyme...but any attendant swelling that has occurred is also removed by way of the abrasive action” caused by the “effective amount of abrasive ingredient” (see Application page 9, first paragraph).

Applicant further respectfully disagrees with the conclusion reached in the Office Action that “undue experimentation” would be required by a user in order to practice the claimed invention. The Office Action states that “abrasive ingredients were not known in the art for treating pain or itch associated with an insect sting or bite”. However, Applicant respectfully submits that “an effective amount of abrasive ingredient” is used by the present claimed composition for the intended purpose of contacting a site and providing an abrasive action that abrades the site thereby removing bodies from the site. Additionally, it is well known in the art that “an anti-itch enzyme” is used for reducing swelling and pain associated with an insect bite and there is no indication in the art of any unpredictable biological response resulting from application of “anti-itch enzymes”. Anti-itch enzymes and their effects are known in the art.

The composition claimed in claims 13 – 19 combines the effects of “an abrasive” and “an anti-itch enzyme” in conjunction with the claimed carrier in an inventive composition to provide an effective treatment for insect stings and/or bite in the above discussed manner which provides improved results over known compositions. The claimed composition provides an improved insect bite treatment whereby upon application, the “anti-itch enzyme” and the “abrasive ingredient” operate simultaneously in combination to counteract the swelling, itch and pain while “effectively draw[ing] the acids mucoids, poisons and similar debris from the site of the sting or bite” (see Application page 9, second paragraph).

In view of the above remarks and amendments to the claims, it is respectfully submitted that claims 13 – 19 are fully enabled under 35 USC 112, first paragraph. Thus, it is respectfully submitted that the Office Action of claims 13 – 19 under 35 USC 112, first paragraph is satisfied and should be withdrawn.

Rejection of Claims 4, 10, 11, 21, 22, 24, 25, 30, 31 and 33 under 35 USC 102(b)

Claims 4, 10, 11, 21, 22, 24, 25, 30, 31 and 33 stand rejected under 35 USC 102(b) as being anticipated by The Daily Telegraph (TDT) (1996) for reasons stated in the Office Action

Claims 4, 22, 24, 25 and 30, 31 and 33 are cancelled by this response and claims 10 and 11 have been amended to be dependent on allowed independent claim 5. Additionally, claim 21 has been amended to include the allowable limitation of “an anti-itch enzyme” therein. Therefore, in view of the above remarks and amendments to the claims, Applicant respectfully submits that the rejection under 35 USC 102(b) with respect to claims 4, 10, 11, 21, 22, 24, 25, 30, 31 and 33 is moot and should be withdrawn.

The Daily Telegraph (1996) fails to show or provide any 35 USC 112 compliant enabling disclosure of the composition as claimed in amended claim 21. Specifically, TDT neither discloses nor suggests a composition “consisting of effective amount of an abrasive ingredient, an itch-reducing enzyme and a carrier for said abrasive ingredient and said itch-reducing enzyme suitable for topical application to the site of the insect bite or sting, wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site” as in the present claimed invention. Therefore, as TDT neither discloses nor suggests each claimed element, it is respectfully submitted that TDT does not anticipate the present invention as claimed in claim 21. Consequently, it is respectfully submitted that the rejection has been satisfied

and should be withdrawn.

Rejection of Claims 13 and 16 under 35 USC 102(b)

Claims 13 and 16 stand rejected under 35 USC 102(b) as being anticipated by Someya (JP361040211A) for reasons stated in the Office Action.

The present invention as claimed in claim 13 describes a pharmaceutical composition for topical application to a site of insect bites and stings to relieve any of itch, pain, and swelling associated therewith. The composition consists of effective amount of an abrasive ingredient and an effective amount of an anti-itch enzyme. The abrasive ingredient and the anti-itch enzyme are dispersed in a water based pharmaceutical carrier comprising effective amounts of polysorbate 60; isopropyl palmitate; pentaerythrityl tetracaprylate, pentaerythrityl tetracaprate; poliwax emulsifying wax NF; cetearyl alcohol; methylparaben; sodium hydroxide; and NaHCO3. Upon application by a user the composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at the site.

Someya specifically discloses a liquid bathing agent composition that eliminates bad smells and cleans skin for a long period of time. The Someya composition is obtained by blending a vegetable protease with a specific amount of salt and a lower alcohol. However, Someya neither discloses nor suggests the claimed composition for the reasons set forth below.

Specifically, Someya neither discloses nor suggests “an abrasive ingredient” as in the present claimed invention. Applicant respectfully disagrees with the assertion made on page 7 of the Office Action that Sodium Chloride is an abrasive. The Office Action erroneously concludes that because Sodium Chloride exists as crystals in its solid form, it

is considered “an abrasive ingredient”. However, because a compound is in a crystalline form does not automatically imply that the composition is “an abrasive ingredient” as in the present claimed invention. The Office Action provides no support for the conclusion reached and is mere speculation. Sodium chloride is known to be highly soluble in water and slightly soluble in alcohol. In view of these well known properties, crystalline sodium chloride would dissolve when introduced into any carrier agent as claimed in the present claimed invention. In fact, sodium chloride would dissolve when introduced into the lower alcohol of Someya. Thus, the sodium chloride would no longer be crystalline and would NOT be able to function as “an abrasive ingredient” as asserted in the Office Action. Moreover, Applicant fails to recognize or be aware of any instance of Sodium Chloride in any form being used as an “abrasive ingredient” in any “pharmaceutical composition”. Furthermore, the present claimed invention discloses that the “abrasive ingredient” and the “anti-itch enzyme” are “dispersed in a water based pharmaceutical carrier”. As sodium chloride is highly soluble in water, sodium chloride could not be used as an abrasive in the present claimed invention because the sodium chloride would dissolve and cease to be in solid crystal form.

Additionally, Someya discloses the carrier as being “a lower alcohol” and preferably “ethanol”. Applicant respectfully submits that the present claimed invention neither discloses nor suggests using a lower alcohol. Rather, the present claimed invention uses “a water based pharmaceutical carrier”. A “lower alcohol” is an alcohol only having between 1 and 7 carbon atoms. Therefore, the elements of the “water based pharmaceutical carrier” claimed in claim 13, as shown below in Table 1, are NOT “lower alcohols” as disclosed by Someya.

Table 1

<u>Element</u>	<u>Chemical Formula</u>
Polysorbate 60	C ₁₇ H ₂₃
Cetearyl alcohol	C ₁₈ H ₃₆ O ₂
Isopropyl palmitate	C ₁₉ H ₃₈ O ₂
Pentaerythrityl tetracaprylate	C ₁₂ H ₂₆ O ₆
Pentaerythrityl tetracaprate	C ₁₂ H ₂₆ O ₆
Poliwax emulsifying wax NF	(C ₁₇ H ₂₃) + (C ₁₈ H ₃₆ O ₂)
Methylparaben	C ₈ H ₈ O ₃
Sodium hydroxide	C ₁₁ H ₁₃ N ₃ O ₃ S

The other claimed element of the “water based pharmaceutical carrier” of the present claimed invention is “NaHCO₃” which is **NOT** an alcohol and thus clearly not contemplated by Someya. Furthermore, Someya provides no additional 35 USC 112 compliant enabling disclosure of carrier agents other than “lower alcohols”. Thus, as Someya neither discloses nor suggests each of the claimed elements of the present claimed invention, Someya cannot anticipate the present claimed invention.

In view of the above remarks and amendments to claim 13, it is respectfully submitted that Someya provides no 35 USC 112 compliant enabling disclosure that anticipates the present invention as claimed in claim 13. As claim 16 is dependent on claim 13, it is respectfully submitted that Someya also does not anticipate the invention of claim 16. Therefore, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

Rejection of Claims 4, 6-8, 10, 11, 21 – 28 and 30 – 33 under 35 USC 103(a)

Claims 4, 6-8, 10, 11, 21 – 28 and 30 – 33 stand rejected under 35 USC 103(a) as being unpatentable over TDT (1996) for the reasons stated in the Office Action.

Claims 4, 22, 24, 25 and 30, 31 and 33 are cancelled by this response and claims 6 – 8, 10 and 11 have been amended to be dependent on allowed independent claim 5. Additionally, claim 21 has been amended to include the allowable limitation of “an anti-itch enzyme” therein. Therefore, in view of the above remarks and amendments to the claims, Applicant respectfully submits that the rejection under 35 USC 103(a) with respect to claims 4, 21 – 28 and 30 - 33 is moot and should be withdrawn.

As claims 6 – 8, 10 and 11 are now dependent on allowed independent claim 5, these claims are now allowable. Thus, it is respectfully submitted that the rejection of these claims is satisfied and should be withdrawn.

Rejection of Claims 13 – 19 under 35 USC 103(a)

Claims 13 – 19 stand rejected under 35 USC 103(a) as being unpatentable over Someya (JP361040211A) in view of Kerr (1998) for the reasons stated in the Office Action.

Someya is discussed above with respect to the rejection of claims 13 and 16 under 35 USC 102(b) and the arguments presented above are incorporated herein by reference. Specifically, Someya neither discloses nor suggests “a pharmaceutical composition...consisting of effective amount of an abrasive ingredient; and an effective amount of an anti-itch enzyme; said abrasive ingredient and said anti-itch enzyme being dispersed in a water based pharmaceutical carrier...wherein upon application by a user said

composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site" as in the present claimed invention.

Kerr merely discusses the use of lavender in bath oils for soothing and relaxation. Similarly to Someya, Kerr neither discloses nor suggests a "pharmaceutical composition...consisting of an effective amount of an abrasive ingredient; and an effective amount of an anti-itch enzyme; said abrasive ingredient and said anti-itch enzyme being dispersed in a water based pharmaceutical carrier...wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site" as in the present claimed invention.

Additionally, with respect to claim 18, Someya alone or in combination with Kerr neither disclose nor suggest "a pharmaceutical composition...consisting of effective amount of an abrasive ingredient; and an effective amount of an anti-itch enzyme; said abrasive ingredient and said anti-itch enzyme being dispersed in a water based pharmaceutical carrier...and **an anesthetic**; and an active ingredient, wherein upon application by a user said composition is able to relieve any of the itch, pain and swelling caused by the insect bites and stings at said site" as in the present claimed invention. As Someya and Kerr are bath products, there would be no reason or motivation to include "an anesthetic" as in the present claimed invention. Someya clearly defines the composition as a protease blended with a salt in a lower alcohol and Kerr is merely concerned with lavender oil. Someya with Kerr provide no 35 USC 112 compliant enabling disclosure of the claimed composition which includes "an abrasive...an itch reducing enzyme...dispersed in a water based pharmaceutical carrier" and further including "an anesthetic" as in the present claimed invention.

Applicant respectfully submits that there is no reason or motivation to combine the liquid bath composition of Someya with the lavender Oil of Kerr if one was seeking to

produce an advantageous bath composition as asserted on page 9 of the Office Action. However, this is not the intention of the present claimed composition. Applicant respectfully submits that the compositions of Someya and Kerr (bath products) are wholly unlike and unrelated to a “pharmaceutical composition for topical application to a site of insect bites and stings to relieve any of itch, pain and swelling associated therewith” as claimed in claims 13 and 18. Applicant respectfully submits that there would be NO motivation to combine Someya with Kerr to obtain the present claimed invention. Bath formulations as in Someya and Kerr are not known for or sought to be used as topical treatments for insect bites and/or stings. Furthermore, there exists no 35 USC 112 compliant enabling disclosure in Someya or Kerr that the disclosed compositions could or should be used as anything other than a bath composition. Thus, Someya and Kerr disclose compositions that are unrelated to the present claimed composition and which are in a non-analogous technical field.

Even if it is proper to combine Someya and Kerr, the combination of these compositions would not produce the present claimed invention. Rather, a combination of Someya with Kerr results in a composition having a preserving enzyme blended with specific amounts of salt and a lower alcohol and further including lavender oil. Kerr merely discloses lavender oil. The combination would combine the lavender oil with a bath composition such as the one disclosed by Someya. The compositions resulting from the combination of Someya with Kerr is NOT equivalent to the “pharmaceutical composition” of the present claimed invention. As discussed above in the Rejection under 102(b), there is no “abrasive ingredient” provided in either Someya or Kerr. Additionally, there is no “water based pharmaceutical carrier” in either Someya or Kerr. Thus, the present invention as claimed in claim 13 is not made unpatentable by Someya and Kerr.

Furthermore, it is respectfully submitted that the addition of “an anesthetic” as in claim 18 would be contrary to teaching of both Someya and Kerr. In fact, an anesthetic

being used in a bath composition would result in unintended negative effects when the product is being used. The “anesthetic” in the present invention is used to further improve a treatment for an insect bite and/or sting by numbing the site. In a bath composition, a numbing agent could harm the user and thus provides an opposite effect to that intended by the present claimed invention. Therefore, it would not be obvious to include “an anesthetic” as in the present claimed invention with a bath composition as disclosed by Someya and Kerr.

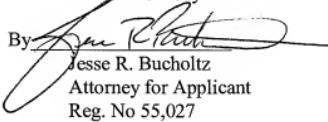
In view of the above remarks and amendments to the claims Someya when taken alone or in combination with Kerr provides no 35 USC 112 compliant enabling disclosure that makes the present invention as claimed in claims 13 and 18 unpatentable. As claims 14 – 17 are dependent on claim 13 and claim 19 is dependent on claim 18, it is respectfully submitted that claims 14 – 17 and 19 are patentable for the same reasons as discussed above regarding claims 13 and 18 respectively. Thus, it is further respectfully submitted that this rejection has been satisfied and should be withdrawn.

Having fully addressed the Examiner's rejections, it is believed that, in view of the preceding amendments, this application stands in condition for allowance. Accordingly then, reconsideration and allowance are respectfully solicited. If, however, the Examiner is of the opinion that such action cannot be taken, the Examiner is invited to contact the applicant's attorney at the phone number below, so that a mutually convenient date and time for a telephonic interview may be scheduled.

No fee is believed due with this response. However, should a fee be due please charge the fee to Deposit Account No. 50-2828.

In light of the foregoing, the application is now believed to be in proper form for allowance of all claims and notice to that effect is earnestly solicited.

Respectfully submitted,
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